REMARKS

I. Prosecution history

The application as filed included a preliminary amendment canceling claims 1-12, 16, 18-39, 46-48 and 51-63, and adding new claims 64-69. Claims 13-15, 17, 40-45, 49, 50 and 64-69 are pending, with all of these claims except claim 13 at issue in the Office Action. Claim 13 stands allowed.

II. Amendments to the specification and claims

The specification has been amended to include the number of the U.S. Patent that issued from the parent application. Also, an inadvertent inclusion of a single word of draft text that does not affect the support for the disclosed and claimed invention was deleted from the paragraph beginning at page 123, line 14. No new matter has been added by way of these amendments.

Claims 15, 17, 42-45, and 65-69 have been canceled. New claims 70-73 have been added. Claims 13, 40, 41, 49, 50 and new claims 70-73 closely track the polynucleotide claims that have been issued in the parent application (U.S. Patent Application No. 09/612,033). Support for amended claims 14 and 64 can be found in Example 4. Support for new claims 70-73 can be found throughout the application. See, for example, pages 11-12, Example 6 and Example 9. None of the amendments made herein were made for reasons pertaining to patentability but rather to expedite prosecution of this application. Applicant reserves the right to pursue the subject matter of any claim, as originally filed or amended, in continuing applications.

III. The rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

The examiner rejected claims 14, 15, 17, 40-45, 49, 50 and 64-69 under 35 U.S.C. § 112, first paragraph, as assertedly lacking written descriptive support and as lacking enablement. In the remarks accompanying the rejection, the examiner acknowledged that the specification is enabling and provides written descriptive support for polypeptides of SEQ ID NOS: 8 and 10 and fusion proteins thereof. [*See* Office Action, pages 3 and 7.] Applicant submits that new claims 70-73, which are of similar scope to the issued polynucleotide claims in the parent application, are also enabled and supported by the specification.

Claims 15, 17, 42, 43, and 65-69 have been canceled and claims 14 and 64 have been amended to recite a polypeptide comprising amino acids 1-170 of SEQ ID NO: 8. Amino acids 1-170 of SEQ ID NO: 8 constitute the common sequence of SEQ ID NOs: 8 and 10 that the examiner recognized as constituting the extracellular domain of a tmst-2 receptor that specifically bound TRAIL. [*See* Office Action, page 4.] Accordingly, the rejections have been rendered moot by amendment. All pending claims are drawn to subject matter either indicated as allowable (i.e., full-length polypeptides or fragments containing the extracellular domain having TRAIL binding activity) or as supported by a disclosure of the extracellular domain specifically binding TRAIL. Therefore, the rejections under 35 U.S.C. § 112, first paragraph, should be withdrawn.

New claims 70-73 correspond in scope to the claims issued in the parent application (U.S. Patent Application No. 09/612,033). New independent claim 70 is drawn to an isolated polypeptide comprising an amino acid sequence encoded by a nucleic acid sequence set forth in SEQ ID NOs: 7 or 9 or an amino acid sequence that is at least 92% identical to an amino acid sequence set forth in SEQ ID NOS: 8 or 10. Supporting disclosure is found, for example, pages 11-12, Example 6 and Example 9. In view of the knowledge in the art and the disclosure of all relevant primary structures (i.e., sequences), the application-as-filed teaches one of skill in the art how to make an isolated polypeptide comprising an amino acid sequence encoded by a nucleic acid sequence set forth in SEQ ID NOs: 7 or 9 or an amino acid sequence that is at least 92% identical to an amino acid sequence set forth in SEQ ID NOS: 8 or 10. Accordingly, new claims 70-73 are also fully supported and enabled by the specification.

IV. The rejection under 35 U.S.C. § 102(a), should be withdrawn.

The examiner rejected claims 14, 15, 17, 49, 50 and 64-69 under 35 U.S.C. § 102(a) as assertedly being anticipated by Kimura et al. (WO 98/43998). This rejection has been rendered moot by amendment. As indicated above in Section III, claims 1, 15, 17, and 65-69 have been canceled and claims 14 and 64 have been amended to recite a polypeptide comprising amino acids 1-170 of SEQ ID NO: 8. Claims 49 and 50 have been amended to depend from either claim 13, which the examiner has indicated as being allowed, or new claims 70-73, which correspond to the polynucleotide claims that have been issued in the parent application.

Kimura et al. fail to teach or suggest an isolated polypeptide comprising an amino acid sequence set forth in SEQ ID NOs: 8 or 10, or a polypeptide comprising amino acids 1-170 or SEQ ID NO: 8. Similarly, Kimura et al. fail to teach or suggest an isolated polypeptide encoded by a polynucleotide comprising a nucleic acid sequence set forth in SEQ ID NOs: 7 or 9 or a polypeptide

that is at least 92% identical to an amino acid sequence set forth in SEQ ID NO: 8 or 10. Absent such a teaching, Kimura et al. cannot anticipate any of the pending claims. Accordingly, the rejection of the above-noted claims under 35 U.S.C. § 102(a) over Kimura et al. has been overcome and should be withdrawn.

V. The rejection under 35 U.S.C. § 103(a), should be withdrawn.

The examiner rejected claims 40-45 under 35 U.S.C. § 103(a) as assertedly being unpatentable over Kimura et al. (WO 98/43998) in view of Goeddel et al. (U.S. Patent No. 5,670,319). This rejection has been rendered moot by amendment. According to M.P.E.P. §§ 2142 and 2143,

> [t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Citing, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); see also M.P.E.P. §§ 2143-2143.03 for decisions pertinent to each of these criteria.

As discussed above in Section IV, Kimura et al. fail to teach or suggest the isolated polypeptides recited in the claims. Goeddel et al., which was cited as teaching that TNF-associated factors can be formulated into a composition comprising a carrier, fail to provide the necessary disclosure lacking from Kimura et al. According to Goeddel et al., "TNF associated factors . . . are defined as a native factor capable of specific association with the intracellular domain of a native TNF-R2, and functional derivatives of such native factor . . . ." (*See*, column 8, lines 59-64.) The "TNF associated factors" of Goeddel et al. are not the polypeptides recited in the claims. Therefore, the disclosure of Kimura et al. in view of Goeddel et al. does not disclose or suggest each limitation of either of claims 40 or 41 (the remaining claims rejected on this basis, claims 42-45 having been canceled by amendment herein). Neither Kimura et al. nor Goeddel et al. disclose or suggest any of the polypeptides of the claims as amended. Thus, even if Goeddel et al. were properly cited as teaching the formulation of polypeptides into pharmaceutical compositions, there is no motive or suggestion to modify the polypeptide of Kimura et al. and then combine that modification of Kimura et al.'s polypeptide with Goeddel et al. to arrive at the claimed subject matter. Finally, in view of the failure of Kimura et al. and Goeddel et al. to disclose or suggest each limitation of any of the rejected

claims as amended, there can be no reasonable expectation of successfully arriving at the claimed subject matter. Thus, the combination of Kimura et al. and Goeddel et al. fails to satisfy any of the three criteria for establishing a *prima facie* case of obviousness for the subject matter of any of the rejected claims as amended. For the foregoing reasons, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been established for any rejected claim pending upon entry of the present amendment. Accordingly, Kimura et al., in combination with Goeddel et al., does not render obvious the subject matter of claims 40 and 41 under 35 U.S.C. § 103(a) and the rejection should be withdrawn.

VI. The nonstatutory obviousness-type double patenting rejection should be withdrawn.

The examiner rejected claims 49 and 50 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 18 of U.S. Patent No. 6,627,199. It is respectfully submitted that the imposition of the rejection is in violation of 35 U.S.C. § 121, which states:

> [a] patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121; *see also* M.P.E.P. § 804.01 (8th ed. rev. 1, Feb. 2003) (setting forth six situations where the prohibition of double patenting rejections under § 121 does not apply). As described in more detail below, the obviousness-type double-patenting rejection is improper because the subject matter recited in claims 49 and 50 was the subject of a restriction requirement imposed during prosecution of the parent application (U.S. Application No. 09/612,033), which issued as U.S. Patent No. 6,627,199.

In the parent application, the examiner imposed a six-way restriction requirement separating the claims into six patentably distinct groups. Claims 49-50, insofar as they were directed to compositions comprising polynucleotides, were assigned to Group I (i.e., claims directed to polynucleotides). Claims 49-50, insofar as they were directed to compositions comprising polypeptides, were assigned to Group II (i.e., claims directed to polypeptides). Applicant elected Group I for continued prosecution and Groups II-VI were withdrawn from further consideration.

Accordingly, in the parent application the examiner concluded that compositions comprising polynucleotides were patentably distinct from compositions comprising polypeptides.

While M.P.E.P. § 804.01 lists exceptions to the prohibition of double patenting rejections under 35 U.S.C. § 121, none of those exceptions is applicable here. See M.P.E.P. § 804.01 (8th ed. rev. 1, Feb. 2003). Specifically, the present application was not filed voluntarily without a restriction requirement made by the examiner — the application was filed in response to the restriction requirement imposed by the examiner during prosecution of the parent application and is directed to the "Group II" claims that were withdrawn from the parent application. Furthermore, the claims herein are consonant with the restriction requirement made by the examiner and have not been changed in material respects from the claims at the time the restriction was made in the parent application. Still further, the restriction requirement imposed during prosecution of the parent application was never withdrawn prior to issuance of that application as the '199 patent. For all these reasons, the double patenting rejection is improper and should be withdrawn.

VII. Conclusion

It is believed that the foregoing amendments and remarks respond to all of the objections and rejections found in the Office Action. If the examiner believes that a telephone conversation would expedite allowance of the claims, she is invited to contact the undersigned at the number indicated below.

The Director is hereby authorized to charge any additional fees required with the filing of this paper to Deposit Account No. 13-2855, under Order No. 01017/35434B.

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Respectfully submitted,

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